

**JUNE 28, 2016
DRAFT AGENDA FOR
MMCC POLICY COMMITTEE
ON PROPOSED DRAFT REVISIONS 10.62.01-35
INCLUDING ACTIONS TAKEN AT
JUNE 14, 2016 MEETING
(VERSION 1)**

Chapter	Chapter Title	Section #	Proposed Revision	Comments
.01	Definitions	(35)(b)	Change “?” to Greek symbol for Delta	ADOPTED
		New definition	“(24a) “Processor agent” means an owner, an employee, a volunteer, an officer, or a director of a licensed processor.”	ADOPTED
.02	General Regulations			
.03	Certifying Physicians			
.04	Patient and Caregiver Registry			
.05	Written Certifications			
.06	Patient and Caregiver Identification Cards			Should every patient be required to obtain an identification card? COMMITTEE VOTED TO NOT CHANGE CURRENT LANGUAGE >> REMAINS AN OPTION OF THE PATIENT
.07	New Condition Approval Process			
.08	Medical Cannabis Grower License	.02F	Strike out “A party” and insert “An investor”.	CHAIR PROPOSES NO CHANGE.

		.03	Strike out the text of .03 and insert “A. Each individual listed in the application addenda in Regulation .02C(1) and (2) shall: (1) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository <i>and the Director of the Federal Bureau of Investigation</i> ; (2) Pay the fee authorized under Criminal Procedure Article, § 10-221(B)(7), Annotated Code of Maryland for access to State criminal history and records; and (3) Request that the individual’s state and national criminal history record information be forwarded to the Commission. B. The applicant shall notify the Commission each individual listed in the application addenda in Regulation .02B(1) and (2) has completed this requirement.”	ADOPTED AS AMENDED (ADD FBI TO CONFORM TO OTHER REGULATIONS) Fixes the problem in criminal history record check regarding obsolete requirement of “two sets of legible fingerprints”
		.05F	Strike out “suspended.” and insert “withdrawn.”	ADOPTED
		.05I(6)(d)(ii)	Strike out “strain” and insert “variety”	ADOPTED
		.06D	Before “Within” insert “(1)”. At the end insert “(2) The applicant shall submit both the stage 2 application fee and the annual license fee	ADOPTED AS AMENDED TO INCREASE TIME TO 14 BUSINESS DAYS

		<p>Rewrite .07 Issuance of License .07A</p>	<p>appropriate for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(1), to the Commission by 4 p.m. of the fourteenth business day following the issuance of the Commission’s notification.”</p> <p>Strike out the text of A. and insert</p> <p>“A. After the notification by the Commission under Regulation 10.62.08.06, (1) if the applicant is an individual, the applicant shall within _____ days, submit to the Commission the three most recent federal tax returns filed by by the applicant, and other financial, personal and background information requested by the commission sufficient to establish to the commission the applicant's capacity to operate a licensed medical cannabis growing enterprise and to establish the applicant's good moral character;</p> <p>(2) if the applicant is a corporation that has not been operational for at least one year before the notification,</p>	<p>Address “audited financial statement” – who needs one, and how much time to submit financial data</p>
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		<p>the owners, officers and directors of the applicant corporation shall, within _____ days, submit to the Commission the three most recent federal tax returns filed by them, and other financial, personal and background information requested by the commission sufficient to establish to the commission capacity of the owners, officers and directors of the applicant corporation to operate a licensed medical cannabis growing enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation; or</p> <p>(3) if the applicant is a corporation that has been operational for at least one year before the notification, the applicant shall, within ____ days, submit to the Commission an audited financial statement, and the owners, officers and directors of the applicant corporation shall, within _____ days, submit to the Commission the three most recent federal tax returns filed by them, and other financial, personal and background information requested by the commission sufficient to establish to the commission capacity of the owners, officers and directors of the applicant corporation to operate a licensed</p>	
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		.07B	<p>medical cannabis growing enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation.”</p> <p>Strike out the text of B. and insert “B. (1) The Applicant shall notify the Commission that its premises, procedures, operations and personnel are ready to be inspected in anticipation of the issuance of a license. (2) The Commission shall notify the applicant when it will carry out the pre-licensing inspection. (3) The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that (i) the criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character; (ii) the applicant’s premises are under the legal control of the applicant; (iii) the premises comply with all zoning and planning requirements; (iv) the premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter; (v) the staff are trained and prepared to follow the procedures; and (vi) the</p>	
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		New .07C	procedures for cultivation and inventory control are as specified in the application. “C. Upon the determination that all of inspections demonstrate that the applicant’s entity and facility comply with the regulations, and is ready to commence business in compliance with the regulations and application, and financial and other background investigations have been completed and passed, the Commission may notify the applicant that it has qualified for a license either to grow medical cannabis or to grow medical cannabis and distribute it, and may issue such license.	MOTION TO CHANGE “MAY” TO “SHALL” WAS DEFEATED.
		New .07D	“D. In the event that the Commission determines to not issue a license, the Commission shall refund the annual license fee promptly. ”	CHAIR PROPOSES THAT THIS NOT BE AMENDED, AND BE ADOPTED AS DRAFTED.
.09	Medical Cannabis Grower Agent	.03B(2)	Strike out “Registry” and insert “Repository”	ADOPTED
.10	Medical Cannabis Grower Premises			
.11	Medical Cannabis Growing Controls			
.12	Inventory Control by Grower	.02A	Strike out A and insert the following: "A. A licensee shall use a perpetual inventory control system as approved by the Commission that identifies and tracks the licensee's stock of medical cannabis from the time the medical cannabis is propagated from seed or cutting to	CHAIR PROPOSES THAT THIS BE ADOPTED WITHOUT AMENDMENT.

			the time it is delivered to a licensed dispensary, licensed processor or a qualifying patient or caregiver."	
.13	Medical Cannabis Shipment Packaging			
.14	Licensed Grower Dispensary Facility			
.15	Medical Cannabis Grower Quality Control	.04A	Strike out A and insert "That is registered by the Commission;"	ADOPTED LAST ITEM OF BUSINESS COMPLETED.
		.05A	Strike out the text of A up through the colon and substitute-- "The weight of each of the following compounds that are contained in one gram of the sample, and whether the detected weight conforms to the specifications for the variety for each of the following compounds:	Modification of suggestion of Chris Charles
		05B (renumber existing B)	For the amount of each compound, in order for the batch to conform to the specifications for the variety, the detected amount must be no less than 90% and no more than 110% of the predetermined standard for the variety.	Revision of Chris Charles proposal
		.05C as renumbered	"Whether the presence of each of the following contaminants exceeds safe levels as designated in the AHP monograph:"	Chris Charles proposal
		.05D	"D. To the Commission each instance in which the batch or lot is out of	May be the wrong place. Objective is to get reports

		.06A	<p>compliance with the specification for the batch or lot.”</p> <p>Strike out A through the colon and substitute:</p> <p>"If the certificate of analysis for the batch indicates the levels of Δ 9-Tetrahydrocannabinol (THC), Tetrahydrocannabinolic Acid (THCA), Cannabidiol (CBD), Cannabidiolic Acid (CBDA), and other active ingredients as determined by the Commission conform to the specifications for the variety, the license grower may:"</p>	<p>on batches or lots out of specification.</p> <p>Chris Charles proposal</p>
		.07A	<p>Strike out A</p> <p>“ The independent testing laboratory shall obtain from each batch and lot from each licensed grower and licensed processor, by means of an appropriate sampling technique, a sufficient number of samples to perform tests for product stability at 6-month intervals to:</p>	<p>Stability testing</p>
		.07B	<p>Strike out B</p> <p>“The independent testing laboratory shall obtain from each batch and lot from each licensed grower and licensed processor, by means of an appropriate sampling technique, a sufficient number of samples to be</p>	<p>Retention of samples to test in event of suspected problems with a batch or lot</p>

			available for (1) testing of the lot or batch in the event follow-up testing is necessary after an adverse reaction report or other matter; and (2) to retain such samples for one year past the date of expiration of the batch or lot.	
.16	Independent Testing Laboratory Registration	.01B(1)	Delete "a non-profit," and insert "an"	AGREED THAT THIS CHAPTER IS TO BE FIRST ORDER OF BUSINESS FOR JUNE 28 MEETING.
		.01B(1)	Insert "ISO/IEC" before 17025	
		.01B(2)	Strike "accrediting" and insert "accreditation"	
		.02B(4)	Delete "and Social Security Number" and insert "and" before "date of birth".	CHAIR RECOMMENDS THAT THIS AMENDMENT NOT BE OFFERED.
		.02C	Should there be any standard for the Commission to deny registration?	CHAIR SUGGESTS THAT LANGUAGE IN CHAPTER 34 IS ADEQUATE
		.02C(1)	Insert "testing" after "independent"	
		New .02C(3)	"Submits evidence that the premises of the independent testing laboratory complies with all zoning and planning requirements;"	Move up from (6)

		.02C(4)	Renumber (5) as (4), and strike period and insert “; and”	For provisional registration either a contract with an accreditation body or evidence of accreditation in another jurisdiction should be sufficient. Bring ITL into seed to sale inventory tracking system
		.02C(5)	Renumber (3) as (5), insert at the end “or”	
		.02C(6)	Renumber (4) as (6), and put a period at the end	
		.05D	“Has established standard operating procedures, in conformity with the Commission’s seed to sale inventory tracking system to provide for adequate chain of custody controls for samples it has obtained.”	
.17	Complaints, Adverse Events, and Recall			
.18	Shipment of Products Between Licensees			
.19	Medical Cannabis Processor License	.02F	Strike out the text of F. and insert “(1) Each individual listed in the application addenda in Regulation .02B(1) and (2) shall: (i) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository; (ii) Pay the fee authorized under Criminal Procedure Article, § 10-221(B)(7), Annotated Code of Maryland for access to State criminal history and records; and (iii)	Clarifies the submission of fingerprint specimens LIKELY TO FOLLOW GROWER LANGUAGE ALREADY DISCUSSED AND ADOPTED.

		<p>.05D</p> <p>.06A(1)</p> <p>.06B.</p>	<p>Request that the individual’s state and national criminal history record information be forwarded to the Commission. (2) The applicant shall notify the Commission once each individual listed in the application addenda in Regulation .02B(1) and (2) has completed this requirement.”</p> <p>Before “Within” insert “(1)”. At the end insert “(2) The applicant shall submit both the stage 2 application fee and the annual license fee for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(3), to the Commission by 4 p.m. of the third business day following the issuance of the Commission’s notification.”</p> <p>Delete “review”</p> <p>Strike out the text of B. and insert “B. (1) The Applicant shall notify the Commission that its premises, procedures, operations and personnel are ready to be inspected in anticipation of the issuance of a license. (2) The Commission shall notify the applicant when it will carry out the pre-licensing inspection. (3) The Commission shall carry out sufficient inspection and background investigation of finances and related</p>	<p>LIKELY TO FOLLOW GROWER LANGUAGE ALREADY DISCUSSED AND ADOPTED -- 14 DAYS</p> <p>LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.</p>
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		<p>.06C</p> <p>.06D</p>	<p>matters to determine that (i) the criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character; (ii) the applicant’s premises are under the legal control of the applicant; (iii) the premises comply with all zoning and planning requirements; (iv) the premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .05 of this chapter; (v) the staff are trained and prepared to follow the procedures; and (vi) the procedures for processing and inventory control are as specified in the application.</p> <p>“C. Upon the determination that all of inspections demonstrate that the applicant’s entity and facility comply with the regulations, and the applicant is ready to commence business in compliance with the regulations and application, and financial and other background investigations have been completed and passed, the Commission may notify the applicant that it has qualified for a license to process medical cannabis, and may issue such license.</p>	<p>LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.</p>
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			"D. In the event that the Commission determines to not issue a license, the Commission shall refund the annual license fee promptly."	LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.
.20	Medical Cannabis Processor Agent	.03B(2)	Strike out "Registry" and insert "Repository"	LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.
.21	Medical Cannabis Processor Premises			
.22	Medical Cannabis Processor Operations			
.23	Medical Cannabis Concentrates and Cannabis-Infused Products	.04A(2)(c)(viii)	"residue of any type of pesticide"	LIKELY TO GENERATE DISCUSSION OF POLICY AND SCIENCE
.24	Medical Cannabis Finished Products Packaging			
.25	Medical Cannabis Dispensary License	.03	Strike out the text of .03 and insert "A. Each individual listed in the application addenda in Regulation .02B(1) and (2) shall: (1) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository; (2) Pay the fee authorized under Criminal Procedure Article, § 10-221(B)(7), Annotated Code of Maryland for access to State criminal history and records; and (3) Request that the individual's state and national criminal history record information be forwarded to the Commission. B. The applicant shall notify the Commission once each individual listed in the application addenda in Regulation .02B(1) and (2) has completed this requirement."	LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.

		.06D	Before “Within” insert “(1)”. At the end insert “(2) The applicant shall submit both the stage 2 application fee and the annual license fee for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(5), to the Commission by 4 p.m. of the third business day following the issuance of the Commission’s notification.”	LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE. – 14 DAYS.
		.06F	“In the event that the Commission determines to not issue a license, the Commission shall refund the annual license fee promptly.”	LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.
		.07B	Strike out the text of B. and insert “B. (1) The Applicant shall notify the Commission that its premises, procedures, operations and personnel are ready to be inspected in anticipation of the issuance of a license. (2) The Commission shall notify the applicant when it will carry out the pre-licensing inspection. (3) The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that (i) the criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character; (ii)	LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.

		<p>.07C</p> <p>.07D</p>	<p>the applicant’s premises are under the legal control of the applicant; (iii) the premises comply with all zoning and planning requirements; (iv) the premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter; (v) the staff are trained and prepared to follow the procedures; and (vi) the procedures for dispensing and inventory control are as specified in the application.</p> <p>“C. Upon the determination that all of inspections demonstrate that the applicant’s entity and facility comply with the regulations, and is ready to commence business in compliance with the regulations and application, and financial and other background investigations have been completed and passed, the Commission may notify the applicant that it has qualified for a license to dispense medical cannabis, and may issue such license.</p> <p>“D. In the event that the Commission determines to not issue a license, the Commission shall refund the annual license fee promptly.”</p>	<p>LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.</p> <p>LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.</p>
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.26	Registered Dispensary Agent	.03B(2)	Strike our Registry and insert "Repository"	LIKELY TO FOLLOW APPROACH TAKEN WITH GROWER LICENSE.
.27	Licensed Dispensary Premises			
.28	Licensed Dispensary Operations			
.29	Licensed Dispensary Packaging and Labeling For Distribution			
.30	Dispensing Medical Cannabis			
.31	Licensed Dispensary Clinical Director			
.32	Records			
.33	Inspection			
.34	Discipline and Enforcement			
.35	Fee Schedule			Should fee for patient identification cards be modified, i.e., REDUCED?

Last edited: 6/15/2016: 1:01 pm (EES)